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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/667,043      | 09/22/2003  | Alan Eskuri          | 1001.1700101        | 7847             |

28075 7590 04/17/2007  
CROMPTON, SEAGER & TUFTE, LLC  
1221 NICOLLET AVENUE  
SUITE 800  
MINNEAPOLIS, MN 55403-2420

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| EXAMINER |
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APANIUS, MICHAEL

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3736

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 04/17/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

eD

|                              |                               |                              |  |
|------------------------------|-------------------------------|------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/667,043 | Applicant(s)<br>ESKURI, ALAN |  |
|                              | Examiner<br>Michael Apanius   | Art Unit<br>3736             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 5-7, 18, 20, 21 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-17, 19 and 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/2/04 &amp; 2/25/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Species 1 corresponding to Figure 2 in the reply filed on 3/28/2007 is acknowledged. The traversal is on the ground(s) that a serious burden has not been shown. Even though the species might be similarly classified, this argument is not found persuasive because different text queries would be required in searches for the different species. For example, the text query would be different for the species in claim 4 and the species in claim 7. Therefore, the search and examination of all the claims would be a serious burden (see MPEP 808.02 (C)). The requirement is still deemed proper and is therefore made FINAL.

2. Claims 5-7, 18, 20 and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Species, there being no allowable generic or linking claim.

### ***Drawings***

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "232" in figure 8. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet

Art Unit: 3736

should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

4. The disclosure is objected to because of the following informalities:
  - a. The abstract does not begin with a complete sentence.
  - b. At page 3, last line, the reference to figure 3 appears to be incorrect.
  - c. At page 16, line 18, it appears that "coil to is used" should be --coil is used--.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 8-10, 12-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Quiachon et al. (US 5,697,380).

Art Unit: 3736

7. Regarding claim 1, Quiachon discloses a guidewire comprising: an elongated inner core member (12) including a proximal section (13) and a distal section, the distal portion including a proximal portion (19) and a distal portion (23); an elongated reinforcing member (36 and 42) disposed about the proximal portion of the distal section such that the distal portion of the distal section is free of the reinforcing member; and an outer member (51) disposed about the distal section of the core member, there being no intervening layer of material between the distal portion of the distal section and the outer member.

8. Regarding claim 2, the reinforcing member comprises nitinol (column 3, line 1).

9. Regarding claim 8, the distal portion of the distal section has a non-circular cross-section (column 2, lines 37-39).

10. Regarding claims 9 and 14, the core member comprises stainless steel (column 2, lines 15-19).

11. Regarding claim 10, the outer member comprises a coil.

12. Regarding claims 12 and 17, the outer member may also comprise a polymer (column 4, lines 32-35).

13. Regarding claim 13, Quiachon discloses a guidewire as noted above. In addition, the outer member is disposed over at least a portion (distal portion of 42) of the reinforcing member.

14. Regarding claim 15, the core member can also be considered to include layers (26 and 31). With this interpretation, the outside diameter of the outer member is substantially equal to the diameter of the proximal region of the core member.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 11, 16 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quiachon et al. (US 5,697,380) in view of Urick et al. (US 5,666,969).

17. Quiachon discloses a guidewire as noted above. An intermediate portion has a smaller cross-sectional area and diameter than a proximal portion (column 2, lines 15-39). The distal portion is flattened (column 2, lines 37-39) which is considered a ribbon profile. Quiachon discloses that the outer member is a coil formed of radiopaque material (column 4, lines 20-22) but does not expressly disclose that the coil is made from stainless steel.

18. Urick teaches making a distal coil from stainless steel in order to provide significantly differing degrees of radiopacity (abstract, lines 9-11) such that the ease and accuracy of locating the guidewire is improved (column 4, lines 20-23).

19. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a stainless steel coil as taught by Urick in the guidewire of Quiachon in order to provide significantly differing degrees of radiopacity such that the ease and accuracy of locating the guidewire is improved.

Art Unit: 3736

20. Claims 3, 4 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quiachon et al. (US 5,697,380) in view of O'Connor et al. (US 6,887,235).

21. Quiachon does not expressly disclose a cut or groove in the reinforcing member.

22. O'Connor teaches a reinforcing member with a helical groove (40 in figure 3A) for the purpose of providing desired torque and flexibility characteristics to the reinforcing member without requiring additional components (column 2, lines 23-26).

23. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have provided the reinforcing member of Quiachon with a helical groove as taught by O'Connor in order to provide desired torque and flexibility characteristics to the reinforcing member without requiring additional components.

24. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quiachon et al. (US 5,697,380) as modified by Urick et al. (US 5,666,969), as applied to claim 11, 16 and 22-24 above, and further in view of O'Connor et al. (US 6,887,235).

25. Quiachon as modified by Urick does not expressly disclose a cut or groove in the reinforcing member.

26. O'Connor teaches a reinforcing member with a helical groove (40 in figure 3A) for the purpose of providing desired torque and flexibility characteristics to the reinforcing member without requiring additional components (column 2, lines 23-26).

27. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have provided the reinforcing member of Quiachon as modified by Urick with a helical groove as taught by O'Connor in order to provide desired torque

Art Unit: 3736

and flexibility characteristics to the reinforcing member without requiring additional components.

### ***Conclusion***

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Johanson et al. (US 5,596,996) discloses a high support nitinol tube guidewire. Noone et al. (US 5,916,178) discloses a steerable high support guidewire with thin wall nitinol tube.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.


30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 3736

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA

  
MARK HINES  
PATENT EXAMINER  
ELECTRONIC CENTER